NU-5532

PATENT

IN THE UNITED STATES PATENT AND TRADMARK OFFICE

Applicant:	Kircher et al.	)
Serial No.:	09/729,498	)
Filed:	December 4, 2000	)
For:	METHOD AND APPARATUS FOR CONTROLLING THE STRATEGY OF COMPOUNDING PHARMA-CEUTICAL ADMIXTURES	)
Group Art Unit:	1743	)
Examiner:	Gordon, Brian R.	)

I hereby certify that this paper is being deposited with the United States Postal Services as FIRST-CLASS mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date.

5/27/04 Date

Registration No. 26974

APPELLANTS' REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants contend that the Lewis et al. patent (hereinafter "Lewis") does not establish an anticipation of independent claims 1 and 24 and therefore of any of the dependent claims. The law of anticipation is straight-forward and long established: An invention is anticipated if the same device, including *all* the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claims in question. *Scripps Clinic and Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226,

1236 (Fed. Cir. 1989); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983). The *identical* invention must be shown by the prior art reference in as much detail as is contained in the patent claim. *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989); *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1267 (Fed. Cir. 1991); Titanium Metals Corp. v. Banner, 778 F.2d 775, 780 (Fed. Cir. 1985).

Lewis does not show several elements of claim 1. The examiner distorts if not misrepresents the scope and content of Lewis, contrary to precedent of the Court of Appeals for the Federal Circuit: It is improper to focus or discriminate on features of prior art references while disregarding its entire disclosure and how its disclosed structure works. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050-51 (Fed. Cir. 1988), citing *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568, 1574 (Fed. Cir. 1987); *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 934, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

Appellants are knowledgeable about the applied prior art because it is technology of the very company they work for. While the examiner states that this is irrelevant because the prior art has been applied under the statutory basis of 35 U.S.C. 102(b), it is a relevant fact because the present application was drafted and claimed with an intimate understanding and knowledge of such prior technology. Appellants are fully aware that the examiner's characterization of the Lewis reference misstates the functionality and capabilities of Lewis.

With regard to the examiner's response to appellant's remarks about incompatibility, Appellants may not have clearly stated their point and will again attempt to make it. In prior office actions, the examiner underlined the word "incompatible" many times as if to emphasize that Lewis taught or suggested the elements of claim 1 (and others) that relate to incompatibility of components. Appellants' point is that incompatibility of components has been known to exist long before Appellants' invention (and long before Lewis for that matter). The fact that an operator considers incompatibility issues in the

Lewis system and manually programs the operation of the system to deal with incompatibility problems does not mean that Lewis anticipates, teaches or suggests claim 1.

More particularly, and as argued in Appellants' appeal brief, Claim 1 claims an apparatus for use in controlling the operation of at least one pharmaceutical compounder which comprises, *inter alia*, "computing means including memory means for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, said memory means including data relating to a plurality of pharmaceutical components" and wherein "said computing means being adapted to receive a prescription admixture, identify the pharmaceutical components thereof, determine the compatibility of pharmaceutical components relative to one another, determine the order in which the components are transferred in preparing the prescribed admixture".

As is clearly set forth in the claim, it is the computing means that performs these functions, not a technician or operator. As is set forth in the specification, data relating to the pharmaceutical components is stored in the memory means and when a prescription is input into the apparatus, the computing means identifies the pharmaceutical components, determines their compatibility relative to one another and determines the order in which the components are transferred in preparing the prescription admixture. This is done in the course of its operation.

Lewis simply does none of this. The Lewis apparatus must be programmed by an operator using a keyboard and possibly another computer, but neither the master microprocessor nor the pumping microprocessor has the capability to identify the specific pharmaceutical components, determine their compatibility and determine the order in which the components are transferred to the final bag during compounding. To the extent that incompatibility of components is an issue during compounding in Lewis, it must be determined to be so by the operator during the input process. The processing means of either of the Lewis or Baxter references cannot determine incompatibility. There is no discussion whatsoever in either Lewis or Baxter about a processing means determining compatibility or

determining the order of transfer of components because neither of them has this functionality. Lewis alludes to the compatibility issue at column 31, lines 7-10 where it states "normally, a rinse will not be conducted unless the next fluid to be pumped is incompatible with the previous fluid, or if the previous fluid pumped was the last fluid to be pumped." In the rinse operation discussion at column 31, lines 58-64, it is clear that rinsing is operator defined:

> "As can be seen in Fig. 37, the first function performed during the rinsing operation is to perform a check to determine if the chamber needs to be rinsed after fluid has been transmitting from a particular source container. An operator of the device may indicate that a rinse is required when information is being entered into the device". (emphasis added)

It is clear that the Lewis apparatus only operates in a particular manner that is established by the operator programming its operation. The operator keys in components and presumably their order as a result of operator knowledge of compatibility or incompatibility of components relative to one another, determines the order in which they are transferred and if the operator believes that a rinse should be done, programs that as well.

The examiner asserts that all computers or automated devices must be programmed at some point in order to function. He also states that it is understood that technology does exist which allows a computer to "learn" after it's been initially programmed to function or run specific routines. With regard to the first assertion, it is largely irrelevant. Claim 1 clearly states that the computing means performs the stated functions based upon data stored in memory "relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture and data concerning the operating characteristics of at least one compounder". Lewis does not store information in this manner, nor does it perform the operations that the computing means performs as stated in claim 1.

The examiner's assertion also ignores the language of claim 1 regarding the memory means having the data as described in the claim. Even if the Lewis memory had the same data, its computing means could not perform the operations that are set forth in claim 1,

inter alia, "said computing means being adapted to receive a prescription admixture, identify the pharmaceutical components thereof, determine the compatibility of the pharmaceutical components relative to one another, determine the order in which the components are transferred in preparing the prescription admixture...". Lewis specifically states that an operator must enter the components of the prescription, determine incompatibilities, determine the order of compounding, whether rinses should be done and where in the order of compounds they should be done. To contend that Lewis anticipates claim 1, misstates the capability and operability of the Lewis apparatus.

With regard to the examiner's contention that a computer can "learn" after it has been initially programmed to function or run specific routines, it is believed that using this as a basis for the rejection is plainly improper[1]. There is no prior art applied or legal precedent supporting this proposition. Moreover, Lewis certainly has not been "initially programmed to function or run specific routines" of the type that are required to perform the operations set forth in claim 1. Lewis simply does not operate in the manner as claimed.

Finally, the examiner identifies text of Lewis (col. 6, lines 44-53) regarding compatibility and then concludes that "the control means does have the ability of determining if the components are compatible and altering the order of dispensing when properly programmed." As is clearly described in Appellants' main brief and also above, it is clear that the manner in which Lewis operates is that the an operator determines compatibility as well as the order of dispensing for every prescription every time. This final comment responding to Appellants' arguments concerning claim 1 clearly demonstrates, yet again, how the examiner has misrepresented the scope and content of the prior art Lewis patent, contrary to the law of the Federal Circuit. (It is improper to focus or discriminate on features of prior art references while disregarding its entire disclosure and how its disclosed structure works. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050-51 (Fed. Cir. 1988), citing

[1] Is every claim to an invention having a processor anticipated by prior art having a processor because the claimed processor can "learn"?

Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1568, 1574 (Fed. Cir. 1987); *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 934, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990)).

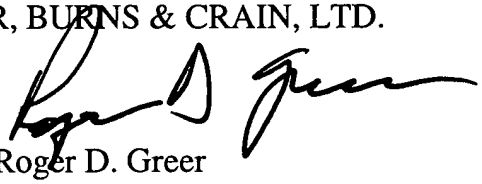
With regard to the other pending claims, to the extent that the above arguments apply to them, Appellants assert them. To the extent they do not apply, Appellants rely on the arguments made in their appeal brief.

CONCLUSION

For the above reasons, the Appellants respectfully request that the Board reverse the Examiner's § 102 and 103 rejections of all pending claims.

Respectfully submitted,

GREER, BURNS & CRAIN, LTD.

By 

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